Premarket Notification – 510(k)

FEB 2 8 2002

ADVIA Centaur CA15-3 Immunoassay

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR 807.92.

The assigned 510(k) number is: K012357

7.1 General Information

Date of Summary Update: December 11, 2001

Applicant:
Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Business Group Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
Phone: 914-524-2446
Fax: 914-524-2500
Ken.edds.b@bayer.com

Owner:
Bayer Corporation
Business Group Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
Establishment Registration No: 2432235

Manufacturer:
Bayer Corporation
333 Coney Street
Walpole, MA 02032
Establishment Registration No: 1219913

Device Name: ADVIA Centaur® CA 15-3 assay

Common or Usual Name: Chemiluminescence immunoassay kit for the determination of CA 15-3 antigen using Bayer Corporation's ADVIA Centaur automated analyzer.

Classification:

Name:	Bayer ADVIA Centaur CA 15-3 Assay
Class:	II
CFR:	21 CFR 866.6010
Product Code:	82 MOI

This submission was prepared in accordance with "Guidance Document for Submission of Tumor Associated Antigen Premarket Notifications".

Substantial Equivalence To: Bayer Immuno-1 CA 15-3

510(k) Number: K964703

7.2 Intended Use

The ADVIA Centaur CA 15-3 assay is an in vitro diagnostic test for the quantitative serial determination of cancer antigen CA 15-3 in human serum using the ADVIA Centaur® System. When used in conjunction with other clinical and diagnostic procedures, serial testing with the ADVIA Centaur CA 15-3 assay is useful for monitoring the course of disease and therapy in metastatic breast cancer patients, and for detection of recurrence in previously treated patients with Stage II, with greater than two positive lymph nodes, or Stage III breast cancer patients. This assay is not intended for use on any other system.

7.3 Device Description

The ADVIA Centaur CA 15-3 assay is a fully automated, two-step sandwich immunoassay using direct, chemiluminescent technology. The Lite Reagent is composed of the monoclonal mouse antibody, DF3, specific for CA 15-3, labeled with acridinium ester. The Conjugate Reagent is composed of the monoclonal mouse antibody 115D8, specific for CA 15-3, labeled with fluorescein. The Solid Phase is composed of purified monoclonal mouse capture antibody, which is covalently coupled to paramagnetic particles. The sample is incubated with both Conjugate Reagent and Solid Phase simultaneously for 20 minutes. After incubation, the immuno-complex is washed and the Lite Reagent is added, incubated for an additional 20 minutes and then washed again. The measured chemiluminescence is directly proportional to the quantity of CA 15-3 antigen in the sample.

7.4 Comparison to the Predicate Device

The ADVIA Centaur CA 15-3 immunoassay kit is similar to the Immuno-1 CA15-3 kit in the indications for use, format, performance characteristics, and results. The ADVIA Centaur tests differ mainly in their signal system as compared to the Immuno-1 principle. In the ADVIA Centaur method, a chemiluminogenic molecule (acridinium ester) is used to replace the Alkaline Phosphatase signal used in the Immuno-1 assay.

7.5 Equivalence to Predicate Device

For 128 samples in the range of 4.0 to 188.6 U/mL, the relationship of the ADVIA Centaur CA 15-3 assay to the Immuno 1™ CA 15-3 assay is described by the following equation (calculated using Deming Regression):

ADVIA Centaur CA 15-3 = 1.018 (Immuno 1) – 4.0 U/mL

The data demonstrate substantial equivalence of the ADVIA Centaur CA 15-3 assay to the FDA-cleared Bayer Immuno-1 CA 15-3 assay as an adjunctive test for use in the management (monitoring) of metastatic breast cancer patients during the course of disease and therapy and for the detection of disease recurrence in Stage II, with greater than two positive lymph nodes, or Stage III breast cancer patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 8 2002

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Diagnostics Corporation
511 Benedict Avenue
Tarrytown, NY 10591

Re: k012357
Trade/Device Name: ADVIA Centaur® CA 15-3™ Assay
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: MOI
Dated: December 12, 2001
Received: December 14, 2001

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012357

Device Name: CA 15-3 Assay for the Advia Centaur

Indications for Use:

The ADVIA Centaur CA 15-3 assay is an in vitro diagnostic test for the quantitative serial determination of cancer antigen CA 15-3 in human serum using the ADVIA Centaur® System. When used in conjunction with other clinical and diagnostic procedures, serial testing with the ADVIA Centaur CA 15-3 assay is useful for monitoring the course of disease and therapy in metastatic breast cancer patients, and for detection of recurrence in previously treated patients with Stage II, with greater than two positive lymph nodes, or Stage III breast cancer patients. This assay is not intended for use on any other system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan S. Alaie

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012357

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)